

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA (Abingdon)

CLERK'S OFFICE U.S. DIST. COURT
AT ABINGDON, VA
FILED

JUN 15 2010

JOHN F. CORCORAN, CLERK
BY: *[Signature]*
DEPUTY CLERK

UNITED STATES OF AMERICA, and the
States of CALIFORNIA, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA,
HAWAII, ILLINOIS, INDIANA, LOUISIANA,
MASSACHUSETTS, MICHIGAN,
MONTANA, NEVADA, NEW HAMPSHIRE,
NEW JERSEY, NEW MEXICO, NEW YORK,
NORTH CAROLINA, OKLAHOMA, RHODE
ISLAND, TENNESSEE, TEXAS, VIRGINIA,
WISCONSIN, the DISTRICT OF COLUMBIA,
and the CITY OF CHICAGO.

Plaintiffs,
Ex rel.

MEREDITH MCCOYD

Plaintiff-Relator,

v.

ABBOTT LABORATORIES, 


Defendants.

Filed Under Seal pursuant to
31 U.S.C. §3730(b)(2)

JURY TRIAL DEMANDED

AMENDED COMPLAINT

1:07cv00081

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I. INTRODUCTION

1. One of the most frightening and devastating diseases of our time is Alzheimer's. It is simultaneously terrifying and heartbreaking. It renders its victims powerless, requiring them to rely upon the conscientiousness of those charged with their care. This case is about a company – Abbott Laboratories – that methodically and recklessly endangered this vulnerable population – those with Alzheimer's and other forms of dementia – through the illegal marketing of a drug that Abbott knew was unapproved for the treatment of Alzheimer's, did not work to treat the disease, and was actually dangerous for use by the elderly. Incredibly, Abbott did not limit its wrongful conduct to preying upon the elderly; it also unlawfully marketed its drug, Depakote, to an array of patient populations, including children, placing them at risk for life altering injury or illness. Abbott's scheme, motivated by money as opposed to a legitimate medical rationale, worked. Sales of Depakote rocketed to over \$1.4 billion per year and compensation for senior executives soared as well.

2. Accordingly, on behalf of the United States of America and on behalf of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, the District of Columbia and the City of Chicago, pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* and similar state and municipal law provisions, Plaintiff and "Relator" Meredith McCoyd files this *qui tam* Amended Complaint against Defendants and alleges:

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3. In violation of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.* and similar state and municipal law provisions, Defendant Abbott Laboratories ("Abbott" or the "Company"), acting alone and in concert with Defendants [REDACTED] collectively with Abbott the "Corporate Defendants"), knowingly presented or caused to be presented false or fraudulent claims to be submitted in violation of the law for payment or approval by federal and state agencies and/or programs by:

- systematically engaging in illegal off-label marketing of Abbott's anti-epileptic drug, Depakote (generic name divalproex sodium);
- furthering the unlawful off-label marketing of Depakote through the transformation of ostensibly independent and unbiased educational and scientific programs, including physician continuing medical education ("CME") programs, into promotional vehicles for Depakote; and
- unlawfully promoting Depakote in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), as amended by the Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), and the Stark Law, 42 U.S.C. § 1395nn, and 42 C.F.R. § 411.350 *et seq.* by providing cash and other incentives to induce doctors to promote and prescribe Depakote, including for off-label uses.

4. A substantial portion of Depakote prescriptions are paid for by Medicare, Medicaid and other government-funded health insurance programs. Prescriptions for uses other than those that are approved by the FDA or included in certain government-

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approved compendia are not reimbursable. *See* 42 U.S.C. §§ 1369b(i)(10), 1396r-8(k), 1369r-8(g)(1)(B)(i).

5. The schemes alleged in this complaint were orchestrated and condoned by the highest levels of Abbott's management, some of whom benefited financially. In carrying out these plans which drained billions of health care dollars from public third party payors, Defendants knowingly placed at risk and caused injury to elderly and pediatric patient populations lacking the capacity to understand the dangers of their own pharmaceutical regimens. Countless elderly nursing home residents and children across the country were given a dangerous drug as a result of marketing practices crafted to maximize Abbott's profitability at the expense of the medical welfare of vulnerable patient populations.

6. Depakote is within the class of drugs known as anti-epileptics. In 1983, the FDA first approved Depakote to treat "simple and complex partial seizures" in adults and children over the age of 10. Since that time, the FDA approved Depakote to treat additional types of seizures for patients over 10 years of age, manic episodes of bipolar disorder for patients over 18 years of age, and for prophylaxis of migraine headaches in adults. Since Depakote's approval for epilepsy in 1983, a number of other new generation anti-epileptics have crowded the market, making it more difficult for Depakote to compete. The number of cases of epilepsy each year remains fairly stable, leaving few opportunities to expand Depakote's on-label sales.

7. Depakote also has significant competition from a number of migraine drugs marketed by other companies. There are also competing medications for bipolar disorder that treat a broader spectrum of the disease than Depakote's indication for acute

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manic or mixed episodes associated with bipolar disorder ("bipolar mania"). Other competing medications also contain FDA indications for the maintenance treatment of mania associated with bipolar disorder, while Depakote's package insert states that the "effectiveness of valproate for long-term use in mania, *i.e.*, more than 3 weeks, has not been demonstrated in controlled clinical trials."¹

8. In order to address the potential stagnation of profits and to exponentially increase its revenue, Abbott embarked upon several centrally-organized, illegal marketing schemes to convince physicians to prescribe Depakote for a number of diseases and disorders for which the drug had (and continues to have) no FDA-approved indication. Abbott's illegal marketing schemes were successful, resulting in the Company posting blockbuster profits for Depakote. Total sales of Depakote in the United States, from 2000 to 2009 were at least \$6.8 billion. Abbott's unlawful practices, as alleged herein, account for a substantial portion of these sales. Abbott's unlawful marketing also benefited top Abbott managers as the Company's revenue growth resulting from its illegal marketing schemes enabled the highest levels of Abbott management to obtain disproportionately large compensation packages.

9. Abbott developed a number of other centrally organized schemes, carried out by its existing sales force dedicated to marketing Depakote for epilepsy, migraine and bipolar mania, to off-label market Depakote for a variety of psychological disorders (*i.e.*, illnesses primarily diagnosed through substantially subjective measures) by blurring the lines of Depakote's narrow indication for bipolar mania.

10. Abbott off-label marketed Depakote to treat:

¹ As part of their scheme, Abbott marketed Depakote, an anti-epileptic drug, as a mood stabilizer.

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- (a) elderly patients suffering agitation associated with dementia or Alzheimer's disease;
- (b) children under age 18 for treatment of mood disorders, ADHD, bipolar depression and developmental delay;
- (c) adult bipolar depression, schizophrenia, and other psychological disorders;
- (d) post-seizure stroke;
- (e) addictive narcotic drug withdrawal;
- (f) children under the age of 10 for epilepsy; and
- (g) elderly patients unable to swallow Depakote capsules by putting Depakote Sprinkles, only FDA-approved for epilepsy, through feeding tubes (a method of administration not included in Depakote's package insert).

11. Starting in about 1998, Abbott embarked on perhaps its most brazen scheme to off-label market Depakote. Abbott targeted elderly patients suffering from Alzheimer's disease and dementia. Abbott seized upon the opportunity to tap into America's aging population and the rapidly expanding geriatric markets (such as long term care, skilled nursing homes and assisted living) by forming an entire sales division devoted to market Depakote off-label to geriatric physicians, pharmacy providers, long term care medical directors and other health care professionals engaged in treating elderly nursing home patients with behavior disorders associated with dementia or Alzheimer's disease. Abbott possessed full knowledge that devoting an entire sales division to

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marketing Depakote to this population for unapproved uses placed countless elderly patients across the nation at risk of serious injury, illness, and death.

12. In furtherance of its scheme to off-label market Depakote to nursing homes and in violation of 31 U.S.C. § 3729 *et seq.*, Abbott paid and/or incentivized Defendants [REDACTED] through direct payments, rebates, and/or free goods and services to assist Abbott in (a) promoting Depakote off-label for agitation associated with dementia, and (b) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In this way, Defendants conspired to knowingly present or cause to be presented false or fraudulent claims to be submitted in violation of the law for payment or approval by federal, state and local governments or public health care programs.

13. In furtherance of its unlawful marketing schemes, Abbott trained and encouraged sales representatives to market the drug for off-label uses without proper clinical evidence of its safety and efficacy for those off-label purposes. Along the same lines, Abbott conspired with Defendants [REDACTED] to increase sales of Depakote for off-label uses in long term care facilities serviced by [REDACTED]

[REDACTED] As a consequence of Defendants' wrongdoing, patients were harmed by extensive off-label, and otherwise unlawful, marketing of Depakote and placed at risk of numerous side effects, including serious liver problems and life-threatening pancreatitis (inflamed pancreas). Children born to women taking Depakote were at risk of serious birth defects.

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14. Elderly patients likewise suffered serious physical and financial harm as a result of Defendants' unlawful conduct, including but not limited to, the disruption or discontinuation of stable treatment regimens and increased costs associated with treating side effects caused or exacerbated by Depakote, including but not limited to, falls associated with sedation and nausea. Moreover, the use of Depakote for agitation in the elderly can be very dangerous if it is used without proper investigation of the causes of the patients' agitation. For example, agitation in the elderly is often caused by physical ailments, such as pneumonia or urosepsis (bacteremia), which may be masked by Depakote's mood altering effects. In such cases, physical conditions like an infection may go untreated, ultimately causing serious injury or death.

15. Government health care payors including Medicare, Medicaid, Tricare, the Veteran's Administration and other public health care plans were harmed because they paid for unauthorized off-label, or otherwise unlawfully induced/caused Depakote prescriptions for which they would not have otherwise paid. Moreover, these Government health care payors also incurred the cost of treating Depakote's side effects.

16. Elderly patients in long term care and skilled nursing facilities suffering from agitation associated with dementia are often eligible for Government health care assistance from Medicare and/or Medicaid and thus, all Defendants knew or should have known that Abbott's unlawful marketing schemes would foreseeably result in the submission of false claims to Government health care payors. This includes payments on behalf of individuals receiving Veteran's Administration and Tricare benefits; moreover, virtually everyone over the age of 65 is eligible for Medicare, which pays for 60 days of care in a skilled nursing facility or a long term care facility and prescriptions through

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Medicare Part D. Elderly patients who cannot care for themselves and exhaust their own personal resources become eligible for free assistance at long term care facilities, including prescription drugs, through Medicaid programs. Thus, Defendants knew that their illegal marketing schemes were directed at individuals whose health care providers would submit false claims to be paid by the Government.

17. Meanwhile, Abbott's profits soared and its top officials received astronomical compensation packages including salary, stocks, and options, at least in part, at the Government's expense. According to Abbott's 2010 Proxy Statement, senior executives at Abbott are paid performance bonuses based on annual sales and participate in a bonus pool made up of a percentage of the Company's net earnings. Similar compensation policies and practices existed in prior years at the Company. Therefore, boosting sales through off-label marketing directly translated (and still translates) to higher bonuses for Abbott's top-level executives. In 2009, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

18. [REDACTED], who took an active role in Abbott's marketing practices, thus personally benefitted from the wrongful conduct alleged in this Amended Complaint.

[REDACTED] knew or should have known that the sales of Depakote exponentially exceeded expectations for the drug's "on-label" uses or intended patient populations. [REDACTED] massive compensation package was due, at least in part, to his own unlawful conduct,

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which included, among other things, condoning the establishment and perpetuation of an entire department of the Company whose goal was to off-label and otherwise illegally market Depakote.

19. Relator Meredith McCoyd has knowledge of Abbott's national scheme to off-label market Depakote. Relator was part of a division, created by Abbott and initially called the Long Term Care Division, whose primary purpose was the off-label marketing of Depakote to physicians [REDACTED]

[REDACTED] This division had representatives serving the entire nation, including the states and municipalities encompassed by this Amended Complaint.

20. Relator was routinely directed to engage in off-label marketing promotions as part of Abbott's centralized national program. She participated in training with Abbott representatives from across the country wherein she learned how to off-label market Depakote. The training sessions were held in a variety of states, including Illinois.

21. Relator was directed and trained by Abbott to engage in a number of tactics to maximize off-label sales of Depakote, including paying physicians to discuss off-label uses of the drug at speaker's programs for other physicians. Abbott developed a centralized process for funneling payments to physicians through intermediary medical organizations, including the Alzheimer's Association, and a company called ABcomm. ABcomm is an Illinois company which served exclusively as a conduit for Abbott to further its unlawful conduct. Abbott referred to its practice of funneling money through intermediaries as "washing the money."

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22. Through its illegal marketing activities, Abbott and Defendants [REDACTED] significantly increased the market for Depakote, which resulted in markedly increased revenue from that drug at the expense of federal, state and local governments. Abbott's off-label Depakote sales represented the fastest growing segment of Abbott's Depakote market. Had federal and state programs, including Medicare, Medicaid, Tricare, Veteran's Administration and other public health care payors known that such prescriptions were induced by illicit incentives or illegal off-label marketing to physicians for non-approved purposes, they would not have reimbursed claims for Depakote.

23. Relator Meredith McCoyd discovered Defendants' wrongful conduct while she was a sales representative employed by Abbott. She conducted her own investigation in furtherance of this False Claims Act *qui tam* action and disclosed her findings to the United States Government and the States prior to filing this action.

II. JURISDICTION AND VENUE

24. Relator brings this action on behalf of herself and on behalf of the United States for violations of the False Claims Act, 31 U.S.C. §§ 3729-3733, the States, the District of Columbia and the City of Chicago for violations of their False Claims Act statutes. This Court has federal subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732 and supplemental jurisdiction over the counts relating to the States, the District of Columbia and the City of Chicago False Claims Act statutes pursuant to 28 U.S.C. § 1367.

25. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because Defendants can be found in and transact business in this

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District. In addition, the acts prohibited by 31 U.S.C. §3729 occurred in this District, 31 U.S.C. §3732(a).

26. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this District and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District.

27. Relator's claims and this Amended Complaint are not based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party, as enumerated in 31 U.S.C. § 3730(e)(3).²

28. To the extent that there has been a public disclosure unknown to the Relator, she is the "original source" and meets the requirements pursuant to 31 U.S.C. § 3730(e)(4)(B).³

III. PARTIES

29. Relator Meredith McCoyd was employed from February 1998 until June 2007 as a pharmaceutical sales representative for Abbott Laboratories, working in Atlanta, Georgia and surrounding areas. Relator was a top performer, winning commendations from Abbott for her sales performance. Working in Abbott's Long Term Care division, which in or about 2004 became known as "Specialty Accounts," Relator exclusively promoted the drug Depakote. Relator has direct knowledge of Defendant Abbott's concerted and repeated efforts to market Depakote for-off-label purposes, as well as, all Defendants' illegal conduct as alleged herein.

² To the extent that conduct alleged in this Amended Complaint occurred prior to March 23, 2010, the prior versions of the False Claims Act are applicable (*i.e.*, 31 U.S.C. § 3730 (e), as amended, October 27, 1986 and May 20, 2009).

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30. Defendant Abbott Laboratories is incorporated in Illinois. Its headquarters and principal place of business is in Abbott Park, Illinois. Abbott engages in the global business of development, manufacturing, marketing, and sale of prescription drugs and other products for the prevention, diagnosis, and treatment of diseases. According to Abbott's Form 10-K filed with the Securities and Exchange Commission ("SEC") dated February 23, 2007, Abbott generated net revenue in excess of \$1.7 billion in the fiscal year ending December 31, 2006. Total sales in 2006 amounted to \$22.5 billion, with Depakote accounting for \$1.2 billion of 2006 sales. A single tablet of Depakote costs \$2.73 to \$3.85, depending on its strength.

31. Defendant [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

³ *Ibid.*

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32. Defendant [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

33. Defendant [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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**IV. STATUTORY AND REGULATORY PROVISIONS APPLICABLE TO
DEFENDANTS' FALSE CLAIMS ACT VIOLATIONS**

A. FEDERAL GOVERNMENT HEALTH PROGRAMS

34. The federal, state and local governments, through their Medicaid, Medicare, Tricare, Veteran's Administration and other Government health care payors, are among the principal purchasers of Abbott's pharmaceutical products.

35. Medicare is a federal government health program primarily benefiting the elderly that Congress created in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS").

36. Congress created Medicaid at the same time it created Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program providing payment of medical expenses to low-income patients. Funding for Medicaid is shared between the federal government and state governments. The federal government also separately matches certain state expenses incurred in administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than does Medicare.

37. Medicaid has broad coverage for prescription drugs, including self-administered drugs. Nearly every state has opted to include basic prescription drug coverage in its Medicaid plan.

38. Tricare is the health care system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of

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active duty personnel and career military retirees and their dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. Tricare is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers.

39. Whereas Tricare treats active duty military and their dependents, the Veterans Administration ("VA") provides health care and other benefits to veterans of the military through its nationwide network of hospitals and clinics.

40. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than 8 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management.

B. THE FALSE CLAIMS ACT AND THE MEDICARE FRAUD & ABUSE/ANTI-KICKBACK STATUTE

41. The Federal False Claims Act provides that any person who knowingly presents or causes another to present a false or fraudulent claim for payment or approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a)(1)(A)&(B). Twenty-four states, the District of Columbia and the City of Chicago have enacted False Claims Act statutes that apply to Medicaid fraud and/or fraudulent health care claims submitted for payment by municipal funds.

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42. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also applies to the state Medicaid programs, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by fines of up to \$25,000 and imprisonment for up to 5 years.

43. The Balanced Budget Act of 1997 amended the Medicare Anti-Kickback Statute to include administrative civil penalties of \$50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a).

44. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit providers from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals paid as a result of the volume or value of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f).

45. Such remunerations are kickbacks when paid to induce or reward physicians' prescriptions. Kickbacks increase government-funded health benefit program expenses by inducing medically unnecessary overutilization of prescription drugs and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices, as physicians may prescribe drug products based on the physician's own financial interests rather than according to the patient's medical needs.

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46. The Medicare Anti-Kickback Statute contains statutory exceptions and certain regulatory “safe harbors” that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protects the Defendants’ conduct in this case.

47. Recently, the Patient Protection and Affordable Care Act (“PPACA”), Public Law No. 111-148, Sec. 6402(g), amended the Medicare Anti-Kickback Statute or “Social Security Act,” 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its “anti-kickback” provisions to be enforced under the False Claims Act. The PPACA also amended the Social Security Act’s “intent requirement” to make clear that violations of the Social Security Act’s anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does “not have actual knowledge” or “specific intent to commit a violation.” *Id.* at Sec. 6402(h).

48. As detailed below, Abbott’s marketing of Depakote repeatedly violated provisions of the Anti-Kickback Statute, which in turn resulted in violations of the False Claims Act because Abbott’s improper kickbacks and incentives induced physicians to prescribe Depakote when they otherwise would not have and many of those prescriptions were paid for by Medicare, Medicaid and other government funded health insurance programs.

49. Knowingly paying kickbacks to physicians (or others such as Defendants [REDACTED] to induce them to prescribe a prescription drug on-label or off-label (or to influence physician prescriptions) for individuals who seek reimbursement for the drug from a federal government health program or causing others to do so, while certifying compliance with the Medicare Anti-Kickback Statute (or while

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causing another to so certify), or billing the Government as if in compliance with these laws, violates municipal, state and federal False Claims Acts.

C. STARK LAW - THE MEDICARE/MEDICAID SELF-REFERRAL STATUTE

50. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn, *et seq.*, known as the “Stark” law, prohibits a pharmaceutical manufacturer from paying remuneration to physicians for referring Medicaid patients to the manufacturer for certain “designated health services,” including drug prescriptions, where the referring physician has a nonexempt “financial relationship” with that manufacturer. 42 U.S.C. § 1395nn(a)(1), (h)(6). The Stark law provides that the manufacturer shall not cause to be presented a Medicare or Medicaid claim for such prescriptions. The Stark law also prohibits payment of claims for prescriptions rendered in violation of its provisions. 42 U.S.C. § 1395nn(a)(1), (g)(1).

51. Knowingly paying physicians to induce them to prescribe a prescription drug on-label or off-label for individuals seeking reimbursement for the drug from a federal government health program or causing others to do so, while certifying compliance with the Stark law (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates municipal, state and federal False Claims Acts.

52. Defendants’ conduct repeatedly violated the Stark law, which in turn resulted in violations of the False Claims Act, because Defendants’ unlawful payments and services to prescribing physicians induced (and still induces) those physicians to prescribe Depakote when they otherwise would not have done so. Many of those prescriptions were paid for by government funded health insurance programs.

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D. FDCA AND FDA REGULATIONS

53. The Food and Drug Administration (“FDA”) regulates drugs based on the “intended uses” for such products. Before marketing and selling a prescription drug, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a).

54. The FDA reviews pharmaceutical manufacturers’ applications for new drugs to determine whether the drugs’ intended uses are safe and effective. *See* 21 U.S.C. § 355. Once a drug is approved for a particular use, doctors are free to prescribe the drug for “non-indicated” or off-label purposes. While doctors may independently request information from drug manufacturers about such off-label uses, with very few exceptions, the FDA prohibits drug manufacturers from marketing or promoting drugs for uses, *i.e.* “indications,” not approved by the FDA. As described above, “off-label” refers to the marketing of an FDA-approved drug for uses that have not undergone FDA review and approval, *i.e.*, for purposes not approved by the FDA.

55. With the exception of purely scientific medical information provided by qualified medical professionals, sales and marketing presentations, promotions, or marketing to physicians for uses other than that approved by the FDA are considered off-label marketing or “misbranding” proscribed by the FDA. *See* 21 U.S.C. §§ 331(a)-(b), 352(a),(f). Additional proscribed marketing activity includes any attempts by pharmaceutical sales representatives to solicit discussions with physicians concerning off-label use.

56. Strong policy reasons exist for strict regulation of off-label marketing. Off-label promotion bypasses the FDA’s strict review and approval process and removes

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the incentive to obtain definitive clinical study data showing the efficacy and safety of a product and, accordingly, the medical necessity for its use.

57. Pursuant to the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, the FDA strictly regulates the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies to market and sell FDA-approved prescription drugs.

58. The FDA interprets "labeling" in its regulations broadly to include items that are "1) descriptive of a drug; 2) supplied by the manufacturer or its agents; and 3) intended for use by medical personnel." 21 C.F.R. § 202.1. The FDCA defines both misleading statements and the failure to reveal material facts in a label or product labeling as "misbranding." 21 U.S.C. § 321(n). Labeling includes, among other things, brochures, booklets, detailing pieces, literature, reprints, sound recordings, exhibits and audio visual material. 21 C.F.R. § 202.1 (l)(2).

59. FDA regulations deem "advertising" to include media-based activities that appear in magazines, newspapers, professional journals and on television, radio, and telephone communications systems. *See* 21 C.F.R. § 202.1(l)(1). Courts have consistently held that oral statements made by a company's sales representative relating to a pharmaceutical product constitute commercial advertising or promotion. *See Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 10 (7th Cir. 1992) (interpreting the Lanham Act).

60. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading "misbrand" a drug in

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violation of the FDCA, 21 U.S.C. §§ 301, 321, 331, 352, 360b, 371; 21 C.F.R. § 202.1(e)(6), (e)(7); 21 C.F.R. § 1.21.

61. Such violations exist where promotional marketing materials and presentations (*i.e.*, advertisements) for an FDA approved drug, among other things:

- Minimize, understate, or misrepresent the side effects, contraindications and/or effectiveness of the drug;
- Overstate or misrepresent the side effects, contraindications, and/or effectiveness of competing drugs;
- Expressly or implicitly promote uses, dosages or combination usage of the drug that is not contained in the FDA approved labeling (*i.e.*, off-label uses);
- Fail to reveal material facts with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement;
- Contain representations or suggestions, not approved or permitted in the labeling, that the drug is better, more effective, useful in a broader range of conditions or patients, safer, or has fewer, or less incidence of, or less serious side effects or contraindications than demonstrated by substantial evidence or substantial clinical experience;
- Present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does;
- Use a quote or paraphrase out of context to convey a false or misleading idea; and/or
- Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

See 21 C.F.R. § 202.1 (e)(4)(5)(6), (7).

62. Oral statements and written materials presented at industry-supported activities, including lectures and teleconferences, provide evidence of a product's intended use. If these statements or materials promote a use inconsistent with the

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product's FDA-approved labeling, the drug is misbranded, as the statements and materials fail to provide adequate directions for all intended uses.

63. Abbott's unlawful marketing of Depakote repeatedly violated the FDCA, which in turn resulted in violations of the False Claims Act, because Abbott's unlawful activity induced physicians to prescribe Depakote, when physicians otherwise would not have done so for prescriptions paid for by government funded health insurance programs. *U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 53 (D. Mass. 2001).

Defendants [REDACTED] conspired with Abbott to violate the FDCA. Had federal, state and local Governments known about the off-label uses for which Depakote was prescribed they would not have paid for the prescriptions. *Id.*

V. SPECIFIC ALLEGATIONS OF DEFENDANTS' FALSE CLAIMS

A. ABBOTT'S PRESCRIPTION DRUG DEPAKOTE

1. Depakote's FDA-Approved Uses and Restrictions

64. Divalproex sodium delayed release tablets marketed by Abbott under the brand name "Depakote DR," were first approved by the FDA in 1983 for treating epilepsy. This drug is approved to treat complex partial seizures in adults and children age 10 and over and "simple and complex absence seizures in adults."

65. In 1989, Abbott received FDA approval for Depakote Sprinkle Capsules ("Depakote Sprinkles"), as a monotherapy and adjunctive therapy, in the treatment of simple and complex absence seizures, and adjunctively in patients with multiple seizure types that include absence seizures. Depakote Sprinkles has not received approval for additional indications.

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66. In May 1995, the FDA issued an additional approval of Depakote DR for treatment of manic episodes associated with bipolar disorder ("bipolar mania"). A manic episode is a distinct period of abnormally and persistent elevated, expansive, or irritable mood. Typical symptoms of mania include "pressured speech," motor hyperactivity, reduced need for sleep, flight of ideas, grandiosity, poor judgment, aggressiveness and possible hostility. The FDA has not approved Depakote DR for the general treatment of bipolar disorder or depression associated with bipolar disorder.

67. In 1996, the FDA further expanded on the approved indications of Depakote DR to include prevention of migraine headaches in adults.

68. In 2000, Abbott introduced an extended-release tablet form of Depakote, called Depakote ER. It was approved by the FDA on September 4, 2000 "for prophylaxis of migraine headaches in adults." *See* FDA Approval Letter dated September 4, 2000.

69. On December 12, 2002, the FDA issued approval for the additional indication of Depakote ER Tablets as monotherapy and adjunctive therapy in complex partial seizures in adults and in simple and complex absence seizures in adults. The FDA extended this usage on September 15, 2003, to include pediatric patients over age 10 for these types of seizures only.

70. In December 2005, Depakote ER was approved for treating acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features. In doing so, the FDA did not approve Depakote for the general treatment of bipolar disorder, depression associated with bipolar disorder, or as a maintenance therapy for bipolar disorder.

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71. Depakote ER and Depakote DR have never been approved for use by children under age 10 (for any use), nor have they been approved for patients under age 18 for uses other than as a treatment for epileptic seizures.

72. Depakote ER, Depakote DR and Depakote Sprinkle Capsules were never approved by the FDA for use in treatment of Alzheimer's disease, other types of dementia, agitation associated with dementia, sundowning, insomnia, post-stroke seizure, ADHD, schizophrenia, mood disorder, types of epilepsy not listed, or narcotic drug withdrawal.

73. Depakote ER prescriptions average anywhere from \$300 to \$2,000 per year per patient.

74. After Depakote DR's approval to treat bipolar mania in 1995, Depakote sales surpassed sales of lithium (FDA-approved for bipolar mania, bipolar depression and maintenance treatment of bipolar disorder generally), becoming the most-prescribed drug for treatment of bipolar mania.

2. Safety Issues: Depakote's Black Box Warnings

75. The FDA does not regulate physicians and, thus, does not prohibit them from prescribing Depakote for unapproved or off-label uses. FDA regulations, however, categorically proscribe and prohibit pharmaceutical companies from marketing their drugs to physicians for off-label uses. To the extent a manufacturer learns about reported cases of severe side effects that are associated with any uses of a prescription drug, the FDA requires the manufacturer to report the side effects to the FDA and the FDA may issue warning letters to physicians and other health care providers.

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76. A warning for all patients taking valproate products has been required in product labeling since 1981. In July 2000, the FDA issued a more stringent “black box warning” (the most urgent warning it can issue short of recall) regarding Depakote’s safety. The FDA required Abbott to change its product labeling and to send letters to health care providers that warned of a life-threatening side effect. The black box warning states in part:

Cases of life-threatening pancreatitis have been reported in both children and adults receiving valproate. Some of the cases have been described as hemorrhagic with rapid progression from initial symptoms to death. Cases have been reported shortly after initial use as well as after several years of use. Patients and guardians should be warned that abdominal pain, nausea, vomiting, and/or anorexia can be symptoms of pancreatitis requiring prompt medical evaluation. If pancreatitis is diagnosed, valproate should ordinarily be discontinued. Alternate treatment for the underlying medical condition should be initiated as clinically indicated.

77. In addition, Depakote is classified by the FDA as a pregnancy “Category D” drug because it should be used by pregnant women only, if without it, the patient would be placed at life threatening risk. The most serious teratogenic effects associated with Depakote include spina bifida, intrauterine growth retardation, skeletal defects, cleft palate, neural tube malformations, and fetal death.

78. In 2007, a safety-related package insert was required warning women of the dangers of birth defects while pregnant and taking this medication. The patient information leaflet states in part:

Before using any of these medications, women who can become pregnant should consider the fact that these medications have been associated with birth defects, in particular, with Spina Bifida and other defects related to failure of the-spinal canal to close normally. Approximately

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1 to 2% of children born to women with epilepsy taking Depakote in the first 12 weeks of pregnancy had these defects (based on data from the Centers for Disease Control). The incidence in the general population is 0.1 to 0.2%. These medications have also been associated with other birth defects such as defects of the heart, the bones and other parts of the body. Information suggests that birth defects may be more likely to occur with these medications than some other drugs that treat your medical condition.

79. The FDA's black box warnings on the use of Depakote remain in effect today.

3. Depakote's Other Warnings, Precautions and Serious Side Effects

80. Depakote also poses certain risks to the reproductive systems of teenage girls, but Abbott representatives were trained to downplay these risks. Specifically, some studies indicate that Depakote causes polycystic ovary syndrome ("PCOS"), the symptoms of which are obesity, irregular menstruation, acne, and excessive amounts or effects of androgenic hormones (*i.e.* masculine hormones). Abbott trained its sales force to discredit the studies that linked Depakote to PCOS and contrast Depakote with Lamictal, another anti-epileptic drug, which is shown to interfere with oral contraceptives. Depakote sales representatives were trained to pitch the purported safety of Depakote for women of childbearing age over Lamictal, by pointing out that teenage girls using oral contraceptives could become pregnant if prescribed Lamictal.

81. Depakote also has a package insert warning for "somnolence in the elderly." In a multi-center trial discussed in Depakote's package insert, a significantly higher proportion of patients on Depakote had somnolence compared to those taking a placebo, forcing discontinuation of the study.

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82. Depakote's sedative effect, heightened when the levels are increased, poses a particular hazard to a geriatric population susceptible to serious life threatening injury associated with falls. Seniors are more likely to fall than younger people, because of slower reflexes, arthritis, reduced vision, and other problems associated with aging. Also, falls have more serious consequences in this population. Abbott specifically knew about the risk of falls in the geriatric population. Melissa Moore, an Abbott Long Term Care Specialist, prepared a PowerPoint training presentation explaining that falls are the second leading cause of death in the United States and "75% occur in older adults." This PowerPoint presentation noted that the Centers for Disease Control estimated that the cost of injuries related to falls would reach \$32.4 billion by year 2020, and \$240 billion for hip fractures by year 2040. While the PowerPoint presentation cited the side effects of prescription drugs as a factor in causing falls, the presentation only mentioned anti-psychotics and not Depakote.

83. The Corporate Defendants knew that federal regulations require that a nursing home facility must ensure an environment free of accident hazard. 42 CFR §483.25(h). Abbott's marketing efforts, in conspiracy with Defendants [REDACTED] [REDACTED] actually increased hazard by causing residents to be placed on a drug that would diminish their coordination and attentiveness to danger, increasing their risk of falls. Accordingly, Defendants' acts in furtherance of their conspiracy caused nursing homes to violate federal regulations and in turn violate the False Claims Act to the extent they were receiving Federal and/or state monies; the receipt of which was premised on compliance with law.

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4. Abbott Marketed Depakote As Means to Circumvent Federally Mandated Oversight Required by OBRA and Federal Regulations

84. In addition, while marketing Depakote as an alternative to anti-psychotic drugs including Risperdal and Seroquel, which were also unlawfully marketed off-label, Abbott trained its sales force to use provisions of a federal statute, the Omnibus Budget Reconciliation Act of 1987 ("OBRA"), as a key selling point for Depakote in nursing homes and other facilities where elderly patients were treated. Specifically, Abbott sales representatives were told by the Company to "inform" geriatric physicians, nurses and consultant pharmacists that the use of Depakote, rather than anti-psychotics, would allow nursing homes to avoid the "use" and documentation requirements of OBRA.⁴

85. Beginning in the late 1960's, Haldol, an antipsychotic drug indicated for schizophrenia, was marketed off-label to nursing homes for use as sedative in lieu of physical restraints. Unfortunately, over the past three decades the off-label use of drugs in nursing homes has spun out of control as drugs with a sedative effect are being used as a substitute for proper staffing. From 1993-2003, the atypical antipsychotics -- including Risperdal, Seroquel, Geodon, Abilify and Zyprexa -- were introduced to the market and off-label marketed to the nursing home sector for their sedative effect. With the sales of these drugs in the geriatric market escalating dramatically, Abbott seized on the opportunity to off-label market its drug Depakote which is not even an antipsychotic but rather an antiseizure medication. In doing so, Abbott competed its drug for off-label use against the atypical antipsychotics which were themselves marketed and used off-label.

⁴ The relevant portions of OBRA were codified within the Social Security Act, 42 U.S.C. § 1395i-3 and are sometimes referred to generally as the "OBRA requirements" or the "Nursing Home Reform Act."

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The confluence of these major drug companies unlawfully competing these drugs against each other and marketing them to such a vulnerable patient population has defied the most basic medical ethics and placed patients at known risk for serious physical harm including death.

86. In 1987, OBRA addressed this over utilization of drugs in nursing homes by mandating that nursing home patients be “free from restraints” including drugs used as “chemical restraints imposed for purposes of discipline or convenience and not required to treat ... medical symptoms.” 42 U.S.C. § 1395i-3 (c)(1)(ii). OBRA regulates the “[u]se of psychopharmacologic drugs” in nursing homes and requires that “[p]sychopharmacologic drugs may be administered only on the orders of a physician and only as part of a plan... designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least annually, an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving such drugs.” 42 U.S.C. 1395i-3 (c)(1)(D)

87. The 1987 legislative history pertaining to OBRA indicated that Congress was concerned that “psychotropic drugs are being used to manage [nursing home] residents for the convenience of nursing facility staffs in a manner that is wholly inconsistent with high quality care of an adequate quality of life.” H.R. Rep. 100-391(I), at 458 (1987), reprint in 1987 U.S.C.C.A.N. 23113-1, 2313-278.

88. OBRA’s implementing regulations mandate that each nursing home resident receive “the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being.” 42 C.F.R. § 483.25. Within this context, the regulations also mandate that “[e]ach resident’s drug regimen be free

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from unnecessary drugs.” 42 C.F.R. §483.25(l). The regulations make clear that an “unnecessary drug” is “any drug” when used in excessive dose, for excessive duration, without adequate monitoring, or without “adequate indications for its use,” in the presence of adverse consequences which indicate the dose should be reduced or discontinued and/or any combination of these factors *Id.* While the OBRA regulations specifically address the use of anti-psychotics in nursing homes, the regulations make clear that any drug can be classified as “unnecessary.” Despite the unambiguous language in OBRA and its implementing regulations, Abbott trained its sales representatives to tell physicians that Depakote was not within the category of drugs, *i.e.*, “psychopharmacologic drugs,” that were subject to the strict documentation and monitoring requirements of OBRA because it was not a “antipsychotic drug.” 42 U.S.C. 1395i-3 (c)(1)(D); 42 C.F.R. § 483.25

89. Abbott’s interpretation of OBRA not only conflicted with the plain meaning of the statute, but the proposed policies of the Health Care Financing Administration (HCFA), which later became the Centers for Medicare and Medicaid Services (CMS). At least as early as 2001, HCFA indicated in draft guidance that it believed the prohibition against using “unnecessary drugs,” included the use of medications used as alternatives to antipsychotics when such drugs were used to manage behavioral symptoms in patients with dementia. In 2006, CMS issued final guidance addressing the use of “unnecessary drugs,” specifically stating that a “‘psychopharmacological medication’ is any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders.” *See*, State Operations Manual Appendix PP - Guidance to Surveyors for Long Term Care Facilities (Effective 12-18-

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06). At the same time, CMS added Depakote to a list of medications that “have the potential to cause clinically significant adverse consequences, that may have limited indications for use, require specific monitoring, and which warrant careful consideration of relative risks and benefit.”

90. By employing a false sales pitch that Depakote’s use by nursing homes would not trigger oversight pursuant to OBRA and that Depakote was an alternative to drugs that were subject to strict use requirements pursuant to OBRA, Abbott wrongfully increased Depakote’s off-label use in facilities treating geriatric patients while aiding and abetting nursing home operators that understaffed their facilities. Abbott’s argument that Depakote was not subject to OBRA but, at the same time, was a replacement for the anti-psychotics being used to treat elderly patients suffering from agitation associated with dementia, was not only disingenuous but also inconsistent, further under-scoring Abbott’s unlawful conduct.

91. To ensure that its message about OBRA reached physicians at nursing homes and other long term care facilities, Abbott also told its sales force that OBRA did not apply to Depakote because Depakote was “so safe” and “did not have the same terrible side effects” associated with anti-psychotics. This representation was false and Abbott knew or should have known that it was false at the time it was made. Moreover, Abbott never provided its sales representatives with copies of OBRA, OBRA regulations or related agency guidelines. Instead, Abbott provided its sales force with a series of articles emphasizing the regulatory scrutiny given to anti-psychotics. Those articles included: (1) *Federal Regulation and the Use of Antipsychotic Medications in Nursing Homes*, Thomas W. Fredrickson, M.B.A., Chad Bolton, MD, M.P.H.; (2) *OBRA*

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Regulations and the Use of Psychotropic Drugs in Long Term Care Facilities, Impact and Implications for Geropsychiatric Care, Alan Stoudmire, M.D. and David A. Smith, M.D.; and (3) *The New OBRA Enforcement Rule: Implications for Attending Physicians and Medical Directors*, Steven A. Levinson, M.D. In this way, Abbott focused its sales force and physicians on only one aspect of OBRA, the use of anti-psychotics.

92. By encouraging its sales force to convert patients from antipsychotics or to add Depakote to an antipsychotic regimen, Abbott sought to have its drug Depakote replace drugs with different indications and different safety and efficacy criteria. Moreover, Abbott encouraged its sales force to compete against drugs that – themselves – were being unlawfully off-label marketed. In doing so, Abbott knowingly caused Depakote to be unlawfully off-label marketed.

93. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] to [REDACTED]

[REDACTED]

[REDACTED] Abbott instructed Relator and other Depakote sales representatives to market Depakote, in these in-services, as a drug that could be prescribed to elderly patients suffering from behavioral problems associated with dementia that would “fly under the radar screen” of OBRA. Relator performed many of such in-services during her tenure at Abbott.

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94. In February 2007, Abbott held a nationwide conference call for its entire Depakote long term care sales force, Depakote marketing staff, and upper level managers, including Wes Mathias, Abbott Regional Account Manager, to discuss the Centers for Medicare and Medicaid Services' guidance issued in September 2006 related to OBRA's restriction of "unnecessary drugs" in nursing homes. During the conference call, Mr. Mathias and an Abbott marketing employee, Anthony Cartwright, instructed Depakote sales representatives to inform physicians treating elderly patients suffering from agitation associated with dementia about methods to circumvent OBRA regulations, such as 42 C.F.R. § 483.25(1), requiring long term care facilities to ensure that residents do not receive drugs in (1) excessive dose, or (2) for excessive duration, or (3) without adequate monitoring, or (4) without adequate indications for its use, or (5) in the presence of consequences that indicate the dose should be reduced or discontinued or (6) any combination of the above (*i.e.*, "unnecessary drugs").

95. Mr. Mathias and other Abbott presenters leading the conference call encouraged long term care representatives, including Relator, to actively approach physicians to discuss the new CMS Guidance and inform them that Depakote would not fall within OBRA's ambit if physicians coded patients as "late onset of bipolar" or "underlying seizure disorder" in the elderly rather than as agitation associated with dementia. According to Abbott's presenters, the added benefit to physicians' mis-coding "agitation associated with dementia" as other diseases or disorders, rather than a drug used to control behavior, was that physicians would not be required to, *inter alia*, monitor blood levels, assess the need for drug holidays or gradual dose reductions,

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96. Another sales representative from Relator's district took notes of the nationwide conference call on the CMS Guidance and circulated them to Mark Krummel, Abbott's National Sales Trainer for Neuroscience, and Suzanna Longnecker, an Abbott Regional Training Specialist, in an email dated February 9, 2007. Recounting Abbott's instructions on the call, Relator's colleague wrote, "[t]his conf call was very helpful – thank you for setting it up! After hearing this call I have a positive outlook on these changes instead of it being a negative thing for us." The attached notes from the call stated: "[u]se Abbott Medinfo.com to get off-label required information to the clinicians." The notes also record the following instructions from Abbott's Mathias: "[w]e know safety of Dpk Long Term! Most pts are on multiple meds. Do GDR [gradual dose reduction] on other meds first. Do GDR on Dpk last." Abbott's instructions to its LTC/SA representatives to encourage physicians to reduce the dosage of other drugs, before Depakote, in elderly populations in long term care facilities had no basis in Depakote's package insert.

97. Defendants' attempt to circumvent the requirements of OBRA by counseling physicians to mis-code illnesses was a component of Defendants' overall scheme to maintain and increase sales of Depakote for off-label uses, such as agitation associated with dementia, in a climate where Government regulators were becoming increasingly concerned with the over-medication of patients and patient safety in long term care facilities.

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**B. ILLEGAL MARKETING SCHEMES PERTAINING TO THE OFF-LABEL USE
OF DEPAKOTE FOR BEHAVIOR DISORDERS RELATED TO DEMENTIA
AND/OR ALZHEIMER'S DISEASE**

**1. In 1998, Abbott Created An Entire Sales Division To Off-label
Market Depakote To Elderly Patients in Institutions**

98. In or about 1998, Abbott created the Long Term Care division ("LTC"), a separate nationwide division of sales representatives exclusively devoted to off-label marketing Depakote to long term care facilities and skilled nursing facilities, most of which overwhelmingly treated elderly patients on Medicare, Medicaid or other public assistance programs. This division was created and/or maintained with the knowledge and consent of Abbott management including [REDACTED]

99. Typically, long term care facility residents are over 65 and not appropriate candidates for "assisted living" settings because they have injuries and illnesses, including mental illness and dementia, rendering them unable to care for themselves. Moreover, the vast majority of long term care facility residents have exhausted their own personal funds and private insurance and, because of their age, qualify for Medicare and Medicaid funds. Some long term care facilities are entirely Government-owned and run, including Georgia's War Veteran's Nursing Home, and state-owned hospitals, operating entirely on public money; however, even privately-owned long term care facilities primarily rely on payments from Medicare and Medicaid.

100. At the inception of Abbott's LTC division in 1998, about 30 sales representatives were assigned to off-label market Depakote to long term care and skilled nursing facilities. Up until at least 2007, Abbott continued to add off-label Depakote sales representatives each year until the number reached approximately 180 as of June 2007.

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101. Until approximately 2004, Abbott utilized four divisions to market Depakote: the LTC division (primarily targeting “agitation associated with dementia”), the Neuroscience Sales division (targeting epilepsy), SR Sales division (targeting psychiatric illnesses), and the Institutional Sales division (serving universities, community mental health centers, and hospitals for a variety of diagnoses). Fearing that regulators would detect its extensive efforts to off-label market Depakote in the LTC division, Abbott combined its Depakote LTC division with other divisions to form what was known as the Specialty Accounts division (hereafter “LTC/SA division”). Representatives working in the new division, including Relator, were known as Specialty Account Executives (“SAEs”). This combination, done to avoid the scrutiny of regulators, was accomplished with the knowledge and consent of [REDACTED]

102. Relator was an Abbott sales representative in the LTC/SA from its inception until 2007 when she left the Company. During her entire tenure at Abbott, as a condition of her continued employment, Relator off-label marketed Depakote in the LTC/skilled nursing setting for elderly patients suffering from a variety of symptoms associated with dementia, such as kicking, screaming, biting, depression, etc., collectively known in the geriatric practice area as “agitation associated with dementia.” In 2004 when Abbott formed LTC/SA division, the Company also required Relator to off-label market Depakote for a variety of illnesses primarily at public mental health centers, which primarily served Medicaid patients, and VA hospitals, which are fully funded by the federal Government.

103. Abbott’s Specialty Accounts division also had representatives marketing Depakote for on-label illnesses, but all sales representatives in Specialty Accounts also

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had responsibility for the off-label marketing of Depakote within their own territory.

Depakote off-label sales were the fastest growing segment of business within the Depakote brand.

104. Abbott encouraged off-label marketing of Depakote through compensation packages that either directly or indirectly rewarded representatives for the success of their off-label marketing activities. For example, Relator McCoyd exclusively marketed Depakote off-label and received bonuses based on the weight (kilograms) of Depakote prescribed at each of the facilities she covered in her territory. The Abbott incentive plan for its LTC/SA sales force in 2007 specifically discussed how bonuses were based on the attainment of "LTC and Non-LTC quota" by LTC/SA representatives and the "corporate product performance." While some of the prescriptions at nursing home facilities were for "on-label" diagnoses, the vast majority were not.

105. In defining its market, Abbott instructed its sales representatives that Depakote's competitors were an array of psychopharmacological drugs, including but not limited to, Risperdal, Seroquel, Geodon, Trileptal, Lamictal, and Abilify. Abbott provided sales representatives with detailed data showing utilization of these drugs by particular physician and institution. Representatives were challenged by Abbott to "convert" physicians or institutions from prescribing these drugs to prescribing Depakote for patients suffering from agitation associated with dementia or encourage physicians to add Depakote to these drugs. Abbott encouraged the conversion from Risperdal, Seroquel, Geodon, Trileptal, Lamictal and Abilify to Depakote or the addition of Depakote to these drugs even though these drugs' indications and side effects are different from Depakote and were also being used off-label.

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106. Abbott's definition of the market and its encouragement to its sales force to convert utilization or cause the adding of Depakote to other drugs marked an extremely dangerous marketing effort. First, the competitor drugs did not have the same indications, side effects or dosing requirements. Second, while some of the atypical antipsychotic medications have indications to be used with Depakote for certain illnesses, the use of Depakote with atypical antipsychotic medications has never been approved to treat agitation associated with dementia.

107. Relator McCoyd and other Abbott LTC/SA representatives used a system, at least up until June 2007, called "Working The Wheel" or "account wheel," to target Depakote off-label marketing to physicians and institutions which Abbott believed would potentially yield the most off-label prescriptions of Depakote for agitation associated with dementia. In this "Wheel" system, Abbott directed its LTC/SA representatives to the "right customers," specifically those able to increase off-label use, including:

- (1) medical directors and consultant pharmacists at large long term care facilities and state hospitals, with a lesser emphasis on the general practitioners and nurses working in these facilities;
- (2) [REDACTED]
[REDACTED] and [REDACTED]
- (3) geriatric psychiatrists, general practitioners, and nurse practitioners who devoted at least two-thirds of their practice to the elderly.

108. In or about January 2004, in furtherance of targeting the "right customers" to increase off-label sales, Abbott began purchasing prescription data from Health Market Science, Inc., which tracked prescription volume and diagnoses data by medical

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institution or institutional pharmacy. Abbott LTC/SA representatives nationwide accessed this prescription data on-line in a spreadsheet format called the Functional Institutional Market Report ("Functional IMR"). The Functional IMR, which was regularly updated, provided Abbott LTC/SA representatives with, among other things:

- (1) the quantity of prescriptions written by physicians at particular medical institutions and/or provided by long-term care pharmacy providers for Depakote, Risperdal, Seroquel, Zyprexa and other psychoactive drugs;
- (2) the diagnoses codes for which these drugs were prescribed; and
- (3) the relative national ranking of each medical institution or long-term care pharmacy based on the volume of Depakote prescriptions written.

109. Abbott also purchased data from [REDACTED] called the LTC Key Physician Tracker ("LTC KPT"), which Abbott LTC/SA representatives used to gather prescribing information about physicians practicing in long term care facilities. Each physician in the LTC KPT was identified by specialty, location and market volume of prescriptions written for Depakote, compared with other drugs such as Haldol, Risperdal, Seroquel and Zyprexa.

110. In addition, [REDACTED] and Abbott developed a "metric" for evaluating physician prescription data for each physician tracked by LTC KPT. The metric sorted each physician into a particular category, which provided the means for Abbott LTC/SA representatives to target long term care physicians, determine "call frequency and messaging" for individual physicians, and "establish share goals" for individual

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physicians (*i.e.*, Depakote sales goals for physicians). These physician categories were: “loyalist,” “grower,” “bleeder,” “potential,” “maintain,” or “low/no.” Abbott defined these categories as follows:

- “Loyalist” physicians frequently prescribed Depakote rather than other psychoactive drugs, such as antipsychotics, for off-label uses promoted by Abbott in the long term care market.
- “Grower” physicians were those Abbott believed would continue to increase prescribing off-label Depakote prescriptions in the long term care market.
- “Bleeder” physicians formerly prescribed Depakote for off-label uses regularly in the long term care market, but were, at that time, prescribing other drugs with more frequency.
- “Potential” physicians were those Abbott believed could be converted to using Depakote, over other comparable drugs, in the long term care market.

111. In short, the LTC KPT’s designations determined, in part, how Abbott LTC/SA representatives spent their time marketing Depakote off-label to physicians, nurses, medical directors and consultant pharmacists. These designations also assisted Abbott and [REDACTED] joint efforts to prescribe Depakote off-label for agitation associated with dementia, as the designations provided LTC/SA representatives with physician specific prescribing habits rather than overall sales by institution.

112. The data pertaining to the number of prescriptions written by each physician for other drugs in other classes, such as atypical antipsychotics, was used by

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Abbott to incentivize its Depakote LTC/SA representatives to "convert" physicians using other drugs such as Risperdal for agitation associated with dementia, even though Risperdal is an antipsychotic and Depakote is an antiepileptic. The atypical antipsychotics also do not have an indication for agitation associated with dementia, but Abbott considered them to be "competitors" from which to capture business in the nursing home setting. By defining these drugs -- which were not the same as Depakote and were themselves marketed off-label -- as competitors, Abbott was furthering its unlawful marketing conduct.

113. In a concerted plan to conceal its wrongful conduct, Abbott forbade its LTC/SA representatives from putting their "call notes" (*i.e.*, brief summaries of discussions with doctors on sales calls, used by managers to track Abbott's sales force's progress) into the Company-wide computer system used by all Abbott sales representatives called "MAX." Instead, LTC/SA representatives were instructed to record in MAX only the office visits with doctors, but to keep separate handwritten notes detailing the subject matter of the calls on paper, which were later faxed to their managers. Abbott's MAX system required sales representatives to document the diagnosis discussed with a physician through use of a "drop-down menu" system. Only diagnoses that fell within Depakote's indication were contained on the drop-down menu, such as epilepsy, migraine and bipolar mania. Abbott managers instructed LTC/SA representatives to document in MAX the physician's name, the date of the call, and one of the on-label diagnoses, even though the sales representatives were primarily detailing long term care physicians and physicians in community mental health centers about illnesses, which were not within Depakote's label.

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2. Abbott Trained Its Sales Force To Off-Label Market Depakote For Elderly Patients

114. In furtherance of a scheme to conceal its wrongful conduct, Abbott conducted “off site” (outside the Abbott Park location) training sessions for sales representatives. These training sessions focused on maximizing Depakote sales through off-label promotion. Because Abbott feared the implications of developing a standardized unlawful sales training program for Depakote held at Abbott’s headquarters, off-label training was provided by outside consultants, including training conducted by Dana Saffel who was at the time of the improper marketing activities, the President & CEO of PharmaCare Strategies, Inc., located in Santa Rosa, Florida.

115. Ms. Saffel was an approved Abbott Speaker and trainer, whose name appears on Abbott’s official approved Speaker List starting in 2004. PharmaCare Strategies, Inc.’s website states that it is “a market development firm that specializes in assisting pharmaceutical manufacturers and pharmacy providers in positioning key products in specialty channels such as long-term care, managed care, Medicaid/Medicare and hospital markets.” The website states that prior to starting PharmaCare Strategies, Inc., Ms. Saffel was the “Vice President of United Pharmacy Services, Inc., a long-term care pharmacy serving over 12,000 residents through Georgia, North Carolina and South Carolina.” Abbott paid Ms. Saffel \$2,000.00 per day for each sales representative being trained. Abbott provided each manager in the LTC/SA channel with funds to train their sales staff; Ms. Saffel’s payments came from such funds. Unlike other Abbott training programs held at Abbott Park, Illinois, Ms. Saffel’s training occurred in a variety of locations across the country.

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116. Abbott Marketing Managers also hand-picked LTC/SA representatives who had developed methods of marketing Depakote off-label to share their techniques with other LTC/SA representatives at regional and national sales meetings. At one such meeting, while Relator and another LTC/SA representative were tapped by Abbott Depakote Trainer, Suzanna Longnecker and District Manager, Jaynie Christensen, to provide off-label sales training for the LTC market, they were explicitly forbidden from preparing or distributing any written materials outlining the training topic. In order to maintain plausible deniability, Abbott upper level management, including Mark Mularski, an Abbott product manager, attended Depakote sales training sessions but purposefully left the room when the off-label training sessions began. Relator was repeatedly told by her managers that while upper level management at Abbott knew about off label training sessions, they did not want to personally bear witness to these sessions.

117. As part of the Abbott training process, LTC/SA representatives were required to memorize and practice "role plays," which were scripted sales calls developed by Abbott to address physician objections to prescribing Depakote off-label for the purposes that Abbott sought to promote. LTC/SA representatives, including Relator McCoyd, practiced the Abbott role plays with other representatives in mock sales scenarios and were critiqued by Abbott managers.

118. Even after the training sessions were completed, Abbott required LTC/SA representatives to regularly practice role plays with supervisors over the telephone, so that Abbott's scripted off-label messages about Depakote became standardized. Abbott required Relator, as well as other LTC/SA representatives, to perform telephone or

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“voicemail role plays” at least once or twice a month. Abbott even held contests to determine which representative had the best role play. The winning “voicemail role play” would often be distributed throughout the Abbott organization as a model.

119. Abbott further encouraged LTC/SA representatives to deliver Abbott’s carefully scripted message about the off-label use of Depakote by setting up monthly contests, within each of Abbott’s district sales areas, that rewarded representatives with monetary awards based on, *inter alia*, message delivery, appropriate use of sales materials, execution of speakers programs, and performance on “role plays” delivered over the phone on “call-ins.”

120. Abbott also developed and trained its LTC/SA representatives to instruct or “detail” physicians about agitation associated with dementia by using Company-approved sales aids, ostensibly designed to promote Depakote’s on-label uses. For example, in 2004 Abbott provided its Depakote LTC/SA sales force with a Slide Kit and Slide Notes (also reduced to a sales aid booklet) called “Make A Difference with Depakote, Skilled Nursing Slide Kit.” The front cover of the booklet shows an elderly man in a wheelchair in pajamas, an elderly woman, and a middle aged man. Slide 3 presents a table of symptoms for each of Depakote’s on-label uses. The symptoms listed for bipolar mania are: aggression, hostility, hypersexuality, elevated expansive mood, extreme irritability, verbal agitation, motor agitation, sleep-wake cycle disturbance, flight of ideas, grandiosity and poor judgment. Abbott specifically designed the sales aid to be used by its LTC/SA representatives in skilled nursing facilities where a large number of elderly patients, who can no longer care for themselves, are being treated for illnesses not primarily for epilepsy, migraine or bipolar mania (all relatively small

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populations of patients in nursing homes). The Skilled Nursing Kit expanded on earlier Depakote sales aids produced by Abbott, including a 1999 sales aid entitled "Recognize the Symptoms," which Relator used in the same manner.

121. Abbott trained Relator to use the bipolar mania "symptoms" chart found in these sales aids as a spring board to question physicians and other health care providers about their patient populations. For example, Relator was instructed to point to the symptoms chart and ask physicians: "Do you treat patients in this nursing home with aggression, hostility etc.?" When the physician responded affirmatively, Relator was taught to segue into an off-label discussion of Depakote's use for agitation associated with dementia. In this way, Abbott trained its sales force to secure illegitimate sales of Depakote by obscuring the differences between bipolar mania and agitation associated with dementia, which have similar symptoms but are distinctly different diseases. By way of example, a cough can be caused by the common cold or lung cancer -- the symptoms are the same but the diseases are so different as to make the focus on the common symptoms irrelevant.

122. Some versions of Abbott's Depakote sales aids, including the Skilled Nursing Kit, also include a variety of non-Depakote and non-drug related data, such as disease statistics, to provide "cover" or as "pretext" for Abbott's promotion of Depakote off-label in certain health care settings, such as skilled nursing homes, where the likelihood of capturing significant legitimate Depakote prescriptions is highly unlikely.

123. For example, Slide 4 of the Skilled Nursing Slide Kit ostensibly addresses "Epidemiology in Bipolar" and states that "5% to 12% of geriatric psychiatry admissions are for bipolar disorder," "9.7% of nursing home patients have bipolar disorder," and

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“10% of bipolar patients develop their illness after age 50.” These statistics, hardly impressive enough to devote the resources of an entire sales force, were used by Abbott to justify its presence in skilled nursing and long term care institutions where they hoped to make it appear that Depakote sales representatives were promoting the drug for bipolar mania, when the true targets were patients suffering from agitation associated with dementia. The “epidemiology in bipolar” data presented in Abbott’s sales aids was also misleading as it related to the use of Depakote, because the data did not indicate how many elderly patients suffer from manic or mixed episodes of bipolar disorder, which was the only FDA approved bipolar indication for Depakote ER.

124. In addition to the Abbott approved sales aids for Depakote, Abbott trained the entire Depakote LTC/SA sales force, including Relator, to detail physicians about prescribing Depakote for agitation associated with dementia using expert consensus guidelines developed in 1998 by physicians and paid for partly by Abbott and other large pharmaceutical companies, which was distributed as a “Special Report” by a journal called “Postgraduate Medicine.” Relator’s trainers told her to tell physicians that Abbott had given an unrestricted grant to “Postgraduate Medicine” to assist in the development of the guidelines.

125. Abbott trained Relator and the entire LTC/SA sales force to “cherry pick” the most useful information from these expert consensus or therapeutic guidelines and provided them with sample dialog to use with physicians.

126. The same or similar expert consensus guidelines were also published in small booklets by Defendants [REDACTED], through grants provided by Abbott. Abbott encouraged LTC/SA representatives to conduct training programs for

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nurses in long term care and skilled nursing facilities served by [REDACTED]
[REDACTED] contracts, using these guidelines to promote Depakote for agitation associated with dementia. Relator's manager directed her to make a PowerPoint presentation using therapeutic guidelines for in-services with physicians and nurses.

127. Also in furtherance of its illegal marketing of Depakote, Abbott encouraged LTC/SA representatives to attend patient and/or caregiver support group meetings, sponsored by third party organizations, providing patients with information about treatment options and emotional support. Abbott encouraged LTC/SA representatives to promote Depakote off-label uses in these support group meetings to patients and caregivers directly. Abbott also paid for and provided materials, such as brochures, for LTC/SA representatives to give directly to those attending these support group meetings. For example, Relator promoted Depakote at programs given by the Alzheimer's Association at various locations called "Doctors and Desserts," which was a patient and caregiver support group meeting.

128. Defendant Abbott's unlawful activities were inconsistent with legal proscriptions against off-label marketing and with Abbott's written policies against off-label promotion, which were little more than distractions, or window dressing, aimed at misleading government enforcement officers.

3. Kickbacks: Abbott Paid Physicians To Induce Prescriptions And Hijacked CME And Other Ostensibly Independent Educational and Scientific Programs For The Unlawful Promotion of Depakote

129. Abbott's marketing strategy included the allocation of substantial resources for its LTC/SA division to "educate" physicians and other health care professionals about off-label uses Abbott promoted, including but not limited to, agitation

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associated with dementia. These resources were allocated to each LTC/SA representative and divided into two different funds: (1) the "war chest" and (2) the "ABcomm" funds. Both funds were primarily used by LTC/SA representatives to pay physicians to spread Abbott's off-label marketing message to other physicians at speaker's programs, dinner lectures, Continuing Medical Education classes ("CMEs"), roundtables and other functions. Relator received between \$20,000 to \$30,000 per year, collectively in war chest and ABcomm funds, to pay for these promotional events.

130. Abbott routinely set timetables for representatives to exhaust the war chest, so as to ensure that representatives were devoting enough time and money to this key component of Abbott's off-label message. Moreover, when LTC/SA representatives failed to exhaust their war chest, they received admonishments from Abbott managers in performance reviews.

131. Abbott provided compensation to physicians who promoted Depakote, either directly or indirectly, usually between \$500 and \$2000 per speech.

132. A document entitled, "Abbott Laboratories, Long Term Care National and Regional Speakers" list indicates, *inter alia*, that Dr. Anton Porsteinsson of the University of Rochester was paid \$2,000 per speech, Dr. Craig Nelson of the University of California at San Francisco was paid \$1,500 per speech, and Dr. Alan P. Siegal of Yale University was paid \$2,500 per speech.

133. Abbott funneled monies through intermediaries, [REDACTED] and associations, such as the Alzheimer's Association, so as to disguise the direct payments to doctors and Abbott's substantial and direct involvement in transforming ostensibly independent educational

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events into promotional vehicles for Depakote. Relator's managers, including Candice Scott, and other upper level Abbott personnel openly referred to Abbott's practice of funneling money through intermediaries as "washing the money."

134. In furtherance of concealing its scheme to promote Depakote's off-label use through physician speaker's events, Abbott encouraged LTC/SA representatives to approach an intermediary to suggest that Abbott fund a speaker's dinner or program to be given by an Abbott selected local physician who routinely used Depakote off-label. Abbott called such doctors "thought leaders" or "champions" when they agreed to speak on off-label Depakote uses. Abbott provided compensation for the physician either directly or indirectly as a payment to the intermediary, usually between \$500 and \$2000 per speech.

135. For example, over Relator's nine year career, Abbott repeatedly directed her to approach medical organizations to suggest that Abbott fund speakers for their educational programs. In so doing, Abbott managers instructed the LTC/SA sales force to suggest speakers handpicked by Abbott, such as Dr. Russell Brown and Dana Saffel who were champions for Abbott. For example, at Abbott's direction, Relator routinely approached Peachford Behavioral Health, Alzheimer's Association, and Georgia American Medical Directors Association ("GAMDA"), among countless other organizations, to suggest that Abbott sponsor a speaker on the use of Depakote to treat elderly patients for agitation associated with dementia, as well as other off-label uses of Depakote.

136. Abbott also provided funds to intermediaries to pay for the meals of physicians attending the lecture, often approaching or exceeding \$100 per plate. Abbott

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Operating Procedures for Program Funding, in effect in March 2006, allowed for up to \$125 per meal for attendees as long as there was a speaker.

137. Abbott recruited physicians who “championed” Abbott’s off-label marketing efforts to be specially trained by Abbott’s corporate marketing department. At the trainings, which typically occurred in luxury hotels in large cities such as New York City, Chicago and Atlanta, Abbott marketing managers provided physicians with talking points and other information over a three day period for use in lecturing at speaker’s programs. Abbott rewarded these physicians by paying for travel, meals and the time associated with training. Abbott also conducted similar training sessions for physicians called “fly aways,” which were all expenses paid junkets to resort locations.

138. As part of the speaker training, Abbott developed written material, including PowerPoint presentations and slides, for use by physicians at speaker’s programs. Abbott encouraged its sales force to provide the materials to speakers who lectured on the off-label use of Depakote for agitation associated with dementia. The materials were also available on a website (www.CENE.com) that doctors and LTC/SA representatives could access called Council for Excellence In Neuroscience Education “CENE,” which was supported by Abbott. These PowerPoint and slide presentations featured off-label uses of Depakote, including the use of the drug to treat agitation associated with dementia.

139. Abbott directed LTC/SA representatives to “coach” physicians who were newly selected to lecture at programs paid for, directly or indirectly, by Abbott. Abbott ensured that the physicians received “talking points,” Abbott-prepared materials, and